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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,544	12/28/2001	Randall Rex Calvert	501059.01	4703
25315	7590	12/21/2004	EXAMINER	
BLACK LOWE & GRAHAM, PLLC 701 FIFTH AVENUE SUITE 4800 SEATTLE, WA 98104			LEWIS, RALPH A	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,544

Applicant(s)

CALVERT, RANDALL REX

Examiner

Ralph A. Lewis

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-91 is/are pending in the application.
- 4a) Of the above claim(s) 61-71, 75-77, 81-83 and 86-91 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37-41 is/are allowed.
- 6) ☒ Claim(s) 1-8, 12, 14-18, 20, 22-25, 27-32, 34-36, 42-48, 50-60, 72-74, 78-80, 84 and 85 is/are rejected.
- 7) ☒ Claim(s) 9-11, 13, 19, 21, 26, 33 and 49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>09142004</u> . | 6) <input type="checkbox"/> Other: _____ |

Election by Original Presentation

Newly submitted claims 61-71, 75-77, 81-83 and 86-91 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The originally presented claims were all directed to an optically transmissive root canal plug whereas the presently identified claims are all directed to a different embodiment of root canal plug having no optically transmissive characteristics. Non-optically transmissive root canal plugs have not been previously searched or considered.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 61-71, 75-77, 81-83 and 86-91 are withdrawn from consideration under the prior art as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Rejections based on Non-Statutory Subject Matter

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 42-60, 71-83 and 87-91 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Independent claims 42, 50, 71 and 77 each positively include the root canal as part of the claimed invention. The root canal, part of a human, is non-statutory subject matter. The examiner suggests claim language such as “the adhesive compound adapted to be interposed between the plug and an interior portion of the root canal” or “for being interposed . . .” to make it clear that applicant is not claiming the patient as part of the invention. Applicant’s attention is directed to *In re Rohrbacher*, 128 USPQ 117 (CCPA 1960) for guidance in claim drafting.

Rejections based on Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 14, 15, 17 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Vari (5,503,559).

Vari discloses an optic fiber 94 (Figure 20, column 9, lines 58-62) that is resilient and sized for extending to the apex (apical portion) of a root canal. Optical fibers are inherently fully polymerized (note this inherence is presumed with applicant’s own fiber optics as applicant’s specification provides no explicit support for the “fully polymerized” limitation). The Vari optic fiber is illustrated abutting the walls on the left hand side of the root canal of the tooth and extends to the apical portion of the root canal. The Vari

optic fiber meets all the structural limitations of applicant's presently claimed "plug." In regard to claim 14, note the elongated support coupled at 94 (Figure 20).

In response to the present rejection applicant amended the claims to require that the plug "substantially abut the walls of the root canal and extend to the apical portion of the root canal when implanted" and argues that his strand of fiber optic is patentable over the Vari strand of fiber optic because the Vari Figure 20 "optical fiber does not substantially abut the walls of the root canal, nor does it substantially occupy an entire volume of the root canal, as clearly shown in Figure 20" (09/14/2004 response, page 19).

Applicant's attention is directed to the following passages in his own specification. "The canals are generally curved and often have irregular cross sectional area along the length of the canal" (specification page 1). "The plug 10 may further be suitably proportioned to fill the root canal in the tooth by providing a range of sizes that are selectable by an endodontist. For example, the plug 10 may be manufactured in standardized sizes or feather tip sizes, or sizes customized to fit a predetermined taper of currently available endodontic rotary instruments that vary in overall length, width, degree of taper, or any combination of length width and taper in order to more closely adapt to the generally unique features of a given root canal." (specification page 9). It is clear, in light of applicant's own specification and disclosure that whether or not a particular fiber optic strand (e.g. the Vari fiber optic of Figure 20, as well as, applicant's fiber optic of Figures 1 and 2) is "suitably proportioned to substantially abut the walls of the root canal of the tooth and extend to the apical portion of the root canal when

implanted” depends on the particular “unique features of a given root canal.” The illustrated Vari fiber optic strand of Figure 20 is capable of meeting the specific claim limitation for some root canals, but not others, just as applicant’s fiber optic strand illustrated in Figure 1 is capable of meeting the claim limitations with respect to some root canals, but not others. If applicant’s disclosed and claimed plug were particularly shaped to match the “irregular cross sectional area along the length of the canal” that would be one thing, but these presently rejected claims include within their scope just a simple cylindrical elongated optic fiber as illustrated in Figure 1. It is a well settled issue of patent law that a known device does not become patentable merely because an applicant desires a different **use** for that prior art device. Applicant points no physical distinction between his claimed optic fiber and the optic fiber disclosed by Vari, but merely argues that the optic fibers are used differently.

Claims 1, 2, 14, 15, 22-24, 42, 43, 46, 50, 51, 54 and 57-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Weissman (5,326,263).

Weissman discloses a plug 11 made of a flexible optically transmissive material for insertion into a prepared root canal. An elongated fiber optic support is coupled to the plug portion. In regard to the intended use limitations that the plug “substantially abut the walls of the root canal and extend to the apical portion of the root canal when implanted,” it is noted that the Weissman optical plug is capable of such a use. Applicant’s own specification admits at pages 1 and 9 that root canals come in various shapes and sizes and further admits at page 10, lines 8-11, that root canals when

prepared are subject to numerous mechanical shaping operations including reaming or filing. The particular root canal opening size is largely dependent on the "unique features of a given root canal" as well as how much the particular root canal is reamed. The examiner is of the firm position the Weissman plug 11 is capable of meeting the limitations for a particular root canal reamed to a size to accommodate the Weissman plug in a sealing manner. Consequently the Weissman plug is physically capable of meeting the functional limitation of how applicant intends for the claimed device to be used.

Applicant's arguments that his claimed device is used differently than the Weissman device, fail to provide for any objectively ascertainable structural distinctions between the claimed device and the prior art device.

Claims 1, 4-7, 12, 14, 17, 18, 20, 22-24, 42, 46-48, 50, 54-56, 72 and 78 are rejected under 35 U.S.C. 102(b) as being anticipated by Billet et al (WO 98/11842)(for purposes of explaining this rejection US 6,183,253 B1 is relied upon as an English translation of the earlier published PCT application).

Billet et al discloses an elongated body comprised of a biologically compatible resilient optically transmissive material (e.g. glass fibers, column 3, line 30, 32) that is fully polymerized (column 3, line 12). It is noted that the Billet et al body also includes materials other than the claimed fully polymerized material, however, applicant uses the open term "comprising" to indicate that the "body" can include materials other than materials that are fully polymerized. . In regard to the "suitably proportioned to

substantially abut the walls of the root canal of the tooth and extend to the apical portion of the root canal" limitation, attention is directed to Figure 2 where the plug body 8 is inserted into a reamed root canal 7 have an irregular cross sectional area along its length wherein the plug is proportioned to substantially abut the walls and extend to the apical portion of the root canal.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 5, 16, 44, 45, 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weissman (5,326,263).

The use of translucent materials, conventional materials (re claim 5, note column 7, lines 18-29) and adhesives with conventional viscosities would have been obvious to one of ordinary skill in the art as a matter of routine practice in carrying out the invention described by Weissman.

Claims 6-8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weissman (5,326,263) in view of Billet et al (WO 98/11842) (for purposes of this rejection US 6,183,253 B1 is relied upon as an English translation of the earlier published PCT application).

Billet et al teach that it is often desirable to include radiopaque materials in fiber optic root canal fillings so that the fillings can be detected by x-ray. To have included conventional fiber optic materials in the fiber optic plug of Weissman so that it could be view by x-ray as taught by Billet et al would have been obvious to one of ordinary skill in the art.

Claims 2, 3, 8, 15, 16, 73, 74, 79 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Billet et al (WO 98/11842) (for purposes of this rejection US 6,183,253 B1 is relied upon as an English translation of the earlier published PCT application).

In regard to claims 2, 3, 15, and 16, Billet et al indicate that the disclosed plug 8 is comprised of a material which is in the form of fibers that are permeable to light (column 3, line 32) but does not explicitly state that the fibers are transparent and/or translucent. One of ordinary skill in the art would readily appreciate and find obvious the use of transparent and/or translucent fibers as the "permeable to light" fibers of Billet et al. In regard to claim 8, the selection of a conventional radiopaque material for the radiopaque material disclosed by Billet et al (column 3, line 18), would have been obvious to one of ordinary skill in the art.

Claims 1-8, 12, 14-18, 20, 22, 23, 25, 27-32, 34-36, 42-48, 50-60, 72-74, 78-80, 84 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martelli et al (EP 0 938 875) in view of Billet et al (WO 98/11842) (for purposes of this rejection US

6,183,253 B1 is relied upon as an English translation of the earlier published PCT application).

Martelli et al disclose a method for obturating a root canal wherein an adhesive is applied a root canal passage (column 3, lines 49-50) an optically transmissive fully polymerized glass fiber plug is then inserted into the root canal and the plug is connected with a light source to conduct light to the root canal polymerizing the adhesive (note column 3, lines 51-54). Martelli et al do not discuss the treatment of the canal to the depth of the apical foramen and the Figures do not appear to illustrate the method of root canal obturation extending to such a depth. Billet et al, however, teach that it is known to clean the root canal to the tip of the apical foramen and then fill it in a sealing manner with a fiber optic plug. To have extended the Martelli fiber optic plug to a length such that it extended to and sealed the apical foramen would have been obvious to one of ordinary skill in the art as taught by Billet et al.

Allowable Subject Matter

Claims 37-41 are allowed.

Claims 9-11, 13, 19, 21, 26, 33 and 49, would be allowable if rewritten in independent form and written to overcome the new matter rejection above.

Action Made Final

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Prior Art

Applicant's information disclosure statement of September 14, 2004 has been considered and an initialed copy enclosed herewith.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication should be directed to **Ralph Lewis** at telephone number **(571) 272-4712**. Fax (703) 872-9306. The examiner works a compressed work schedule and is unavailable every other Friday. The examiner's supervisor, Kevin Shaver, can be reached at (571) 272-4720.

R.Lewis
December 16, 2004


Ralph A. Lewis
Primary Examiner
Au3732